

REMARKS

The Office Action dated September 7, 2005, has been received and reviewed.

Claims 34-70 and 72-120 are currently pending and under consideration in the above-referenced application. Claims 100-109 have been allowed. Claims 43, 46, 48-51, 61, 62, 65-69, 75, 78, 80-83, 85-87, 95-99, 111, and 116-120 are directed to allowable subject matter. Claims 34-42, 44, 45, 47, 52-60, 63, 64, 70, 72-74, 76, 77, 79, 84, 88-94, 110, and 112-115 stand rejected.

Reconsideration of the above-referenced application is respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 34-42, 44, 45, 47, 52-60, 63, 64, 70, 72-74, 76, 77, 79, 84, 88-94, 110, and 112-115 stand rejected under 35 U.S.C. § 102(e) for being drawn to subject matter that is allegedly anticipated by the subject matter disclosed in U.S. Patent 6,200,271 to Kück et al. (hereinafter "Kück").

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

In the rejection of claims 34-42, 44, 45, 47, 52-60, 63, 64, 70, 72-74, 76, 77, 79, 84, 88-94, 110, and 112-115, it has been asserted that the time periods and ranges described in Kück are "approximately" the same as corresponding time periods and ranges recited in the claims at issue.

The Fourth Edition of the American Heritage Dictionary of the English Language (Houghton-Mifflin Co. 2000) defines the term "approximate" to mean "[a]lmost exact or correct" and "[v]ery similar; closely resembling." It is respectfully submitted that one of ordinary skill in the art would understand the term "approximate," as used in the claims of the above-referenced application, to have a meaning that approximates this exemplary definition of the term.

Accordingly, it is respectfully submitted that the six second “before” rebreathing phase disclosed in Kück does not last for the claimed approximately, or almost exactly, eighteen seconds to approximately, or almost exactly, forty-two seconds, the minimum claimed time period being three times as long as six seconds. Further, the examples of fifty second and sixty second “during” rebreathing phases that have been provided in Kück is not the approximately, or almost exactly, eighteen seconds to approximately, or almost exactly, forty-two seconds, the upper end of which range is far less than the fifty and sixty second time periods disclosed by Kück.

Thus, Kück does not expressly or inherently describe a method that includes evaluating respiration during two different ventilation states that have durations of “approximately eighteen seconds to approximately forty-two seconds,” as recited in independent claims 34 and 110.

For the same reason, Kück lacks any express or inherent description of inducing a change in effective ventilation for a first duration of time, then removing the change in effective ventilation for a second duration of time, with each of the first and second durations lasting from approximately eighteen seconds to approximately forty-two seconds, as required by the method of independent claim 84.

Additionally, with respect to the method recited in independent claim 52, it is again submitted that Kück neither expressly nor inherently describes a method that includes evaluating respiration of a subject during a first ventilation state, evaluating respiration of a subject during a second ventilation state that immediately follows the first ventilation state, and evaluating respiration of the subject during *another* first ventilation state, which immediately follows the second ventilation state (*i.e.*, 1, 2, 1). Thus, any repetition of this pattern, to which independent claim 52 is not limited, would follow the first, second pattern, with the term “immediately” indicating that no ventilation states are interleaved between first and second ventilation states. Thus, any such repetition would follow a 1, 2, 1, 2, . . . pattern.

Instead, Kück clearly describes a method in which respiration is evaluated during each of a sequential “before,” “during,” and “after” rebreathing phase (*i.e.*, 1, 2, 3). The “before” and “after” rebreathing phases of the method of Kück are not the same. In the “before” rebreathing

phase, normal breathing occurs and “normal,” or baseline, VCO_2 and CACO_2 measurements may be obtained. *See* col. 9, lines 55-57. In the “during” rebreathing phase, rebreathing occurs and the subject’s VCO_2 and CACO_2 are elevated. The “after” rebreathing phase lasts from termination of rebreathing until the subject’s respiration returns to “normal,” or until an “accurate determination of VCO_2 and CACO_2 [sic]” may be made. Col. 9, lines 55-57. The algorithms disclosed in Kück account for differences in respiratory gases during these three distinct phases. *See, e.g.,* col. 10, lines 53-55 and 62-64. Once the subject’s respiration has returned to “normal,” another “before” rebreathing evaluation of the subject’s respiration may be conducted. Thus, any repetition of the method described in Kück follows a 1, 2, 3, 1, 2, 3, . . . pattern.

Moreover, assuming solely for the sake of argument that a combination of an “after” rebreathing phase and a subsequent “before” rebreathing phase of Kück could be considered the same as a “first ventilation state” of independent claim 52 (or, more specifically, the “another” first ventilation state), this combined rebreathing phase would not last for “approximately eighteen seconds to approximately forty-two seconds.” Instead, the disclosure of Kück (*see* Figs. 4 and 5) is limited to a combined “after” and “before” rebreathing phase having a duration of ninety seconds, which is far greater than approximately, or almost exactly, forty-two seconds.

Kück also includes no express or inherent description that the second incidence of a first ventilation state may have a duration of “approximately eighteen seconds to approximately forty-two seconds,” as recited in independent claim 52.

The differential Fick technique of independent claim 70 *consists essentially of* a first phase and a second phase. In the first phase, a change in effective ventilation is induced. In the second phase, which follows the first phase, the change in effective ventilation is not present. As the disclosure of Kück is limited to a rebreathing technique that includes three distinct phases (again, the “before” and “after” rebreathing phases of Kück’s technique are not the same – *see, e.g.,* col. 9, lines 55-57), it cannot anticipate a technique that *consists essentially of* only two phases.

Therefore, the disclosure of Kück does not anticipate each and every element of any of independent claims 34, 52, 70, 84, or 110, as would be required to maintain the 35 U.S.C. § 102(e), rejection of these claims.

Each of claims 35-42, 44, 45, and 47 is allowable, among other reasons, for depending directly or indirectly from claim 34, which is allowable.

Claim 36 is additionally allowable since Kück does not expressly or inherently describe “repeating evaluating respiration of [a] subject during another first ventilation state *immediately following* evaluating respiration of the subject during [a] second ventilation state.” (Emphasis supplied). Instead, Kück describes evaluating respiration of a subject during a first state (the “before” phase), then a second state (the “during” phase), then a third state (the “after” phase) before repeating the first state of the three-state process.

Claim 45 is further allowable because Kück includes no express or inherent description of evaluating respiration of a subject during a second ventilation state in which the subject breathes “gas or a gas mixture comprising at least a concentration of oxygen present in air.” Instead, the description of Kück is limited to a second ventilation state in which a subject breathes gases with an increased concentration of carbon dioxide.

Each of claims 53-60, 63, and 64 is allowable, among other reasons, for depending either directly or indirectly from claim 52, which is allowable.

Claim 53 is also allowable since Kück neither expressly nor inherently describes that first and second ventilation states may be effected for substantially a same duration. Rather, the disclosure of Kück is limited to one technique in which a “before” phase lasts for six seconds, a “during” phase lasts for about 50 seconds (which is significantly greater than six seconds), and an “after” phase lasts for an unspecified period of time, and to another technique in which the 60 second “during” phase is longer than both the 50 second “before” phase and the 40 second “after” phase.

Claim 54 is further allowable since Kück does not expressly or inherently describe that respiration may be evaluated during first, second, and another first ventilation states having

substantially the same durations. Instead, Kück describes that respiration may be evaluated during a first state that lasts for six seconds, a second state that lasts for about 50 seconds, and a third state that lasts for an unspecified period of time, or that respiration may be evaluated during a first state that lasts for 50 seconds and a second state that lasts for 60 seconds, and a third state that lasts for 40 seconds.

Claims 55-57 are allowable because Kück includes no express or inherent description that respiration may be respectively evaluated during a first, second, or another first ventilation state that lasts for about thirty seconds. Rather, the description of Kück is limited to a first ventilation state that for six seconds or 50 seconds and a second ventilation state lasts for about 50 seconds or for 60 seconds, none of which is even close to 30 seconds.

Claim 64 is further allowable because Kück includes no express or inherent description of evaluating respiration of a patient during a second ventilation state in which the patient breathes “gas or a gas mixture comprising at least a concentration of oxygen present in air.” Instead, the description of Kück is limited to a second ventilation state in which a patient breathes gases with an increased concentration of carbon dioxide.

Claims 72-74, 76, 77, and 79 are each allowable, among other reasons, for depending directly from claim 70, which is allowable.

Claim 72 is also allowable because Kück lacks any express or inherent description of first and second phases that both have durations of about thirty seconds. Rather, Kück describes a process in which a “before” phase lasts for six seconds, a “during” phase lasts for about 50 seconds, and an “after” phase lasts for a unspecified period of time, and to a process in which a “before” phase lasts for 50 seconds and a “during” phase lasts for 60 seconds, and an “after” phase lasts for 40 seconds. All of these time periods differ significantly from the “about thirty seconds” required by claim 72

Claims 88-94 are each allowable, among other reasons, for depending either directly or indirectly from claim 84, which is allowable.

Claim 88 is also allowable since Kück neither expressly nor inherently describes that a first duration of time of inducing a change in effective ventilation and a second duration of time of removing a change in effective ventilation may substantially be the same.

Claim 91 is also allowable since Kück does not expressly or inherently describe that a change in effective ventilation may be induced for about thirty seconds and removed for about thirty seconds. Instead, Kück teaches that a “before rebreathing” state lasts for six seconds or 50 seconds and that a “rebreathing” state lasts for 50 seconds or 60 seconds, and that an “after rebreathing” state, or recovery period, that follows the “rebreathing state” may last for an unspecified period of time or for 40 seconds.

Claims 113-115 are each allowable, among other reasons, for depending directly or indirectly from claim 110, which is allowable.

In view of the foregoing, it is respectfully requested that the 35 U.S.C. § 102(e) rejections of claims 34-42, 44, 45, 47, 52-60, 63, 64, 70-74, 76, 77, 79, 84, 88-94, 110, and 112-115 be withdrawn.

Rejections under 35 U.S.C. § 102/103

Claims 34, 35, 37-42, 44, 45, and 47 have been rejected under 35 U.S.C. § 102(e) or, in the alternative, under 35 U.S.C. § 103(a) for being directed to subject matter that is respectively anticipated by or obvious in view of the disclosure of U.S. Patent 6,106,480 of Gama de Abreu et al. (hereinafter “Gama de Abreu”).

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim

limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Like the rejection based on the disclosure of Kück, this rejection is based on an improper meaning of the term "approximately." The disclosure of Gama de Abreu is limited to a rebreathing technique that includes a nonrebreathing period having a duration of sixty seconds and a rebreathing period that lasts for thirty seconds. The sixty second nonrebreathing period of Gama de Abreu is not "approximately eighteen seconds to approximately forty-two seconds" in length. Thus, Gama de Abreu does not anticipate each and every element of independent claim 34, as would be required to maintain the 35 U.S.C. § 102(e) rejection of that claim.

With respect to the alternative, 35 U.S.C. § 103(a) rejection of independent claim 34, an *assumption* by the Office that a nonrebreathing period having a duration of less than sixty second "would perform equally well" in the method of Gama de Abreu does not amount to a motivation or suggestion to one of ordinary skill in the art at the time the above-referenced application was filed to modify the teachings of Gama de Abreu in the manner that has been asserted. In fact, the Office has not presented any reference that teaches or suggests a differential Fick technique with two phases that have as short durations as those recited in independent claim 34. As such, the Office's assumption and, thus, the 35 U.S.C. §103(a) rejection of claims 34, 35, 37-42, 44, 45, and 47 appears on its face to be based on nothing more than improper hindsight.

Claims 35, 37-42, 44, 45, and 47 are each allowable, among other reasons, for depending directly from claim 34, which is allowable.

Accordingly, withdrawal of the 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a) rejections of claims 34, 35, 37-42, 44, 45, and 47 is respectfully requested.

CONCLUSION

It is respectfully submitted that each of claims 34-70 and 72-120 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing

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allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brick G. Power". The signature is fluid and cursive, with the first name "Brick" being more prominent.

Brick G. Power
Registration No. 38,581
Attorney for Applicants
TRASKBRITT, PC
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

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